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Effects on healthcare utilisation of case management for frail older people: a randomized controlled trial

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Abstract

Various healthcare interventions have been launched targeting the growing population of older people. The objective of this study was to investigate the of a case management intervention for frail old people (aged 65+ years) effects on healthcare utilisation.

The study was conducted in a municipality in southern Sweden and included people aged 65+ years who lived in their ordinary homes, were dependent in two or more activities of daily living, and had at least two hospital admissions, or four physician visits, in the previous year. One-hundred-fifty-three participants were randomly assigned to either an intervention (n=80) or a control group (n=73). The one-year intervention comprised home visits, at least once a month, by case managers. Group differences were investigated 6-12 and 0-6 months before, and 0-6 and 6-12 months after, baseline.

The intervention group had, compared to the control group, significant lower mean number (0.08 vs. 0.37, p=0.041) and proportion (17.4 vs. 46.9%, p=0.016) of emergency department visits not leading to hospitalisation 6-12 months after baseline. The intervention group also had a significantly lower mean number of visits to physicians in outpatient care 6-12 months after baseline (4.09 vs. 5.29, p=0.047).

The effect on emergency department visits not leading to hospitalisation meant that those in the control group were more likely to visit the emergency department for reasons that did not require hospitalisation, suggesting that they may have been less monitored than the intervention group. The intervention has the potential to reduce the burden on outpatient care and emergency department.

Trial registration: ClinicalTrials.gov NCT01829594

Keywords: Case management, Frail elderly, Healthcare utilisation, Randomised controlled trail, Inpatient care, Outpatient care

Highlights

- Case management had effect on some emergency department visits
- Case management had effect on visits to physicians in outpatient care
- Case management had no effect on hospital admissions
- Case management had no effect on length of stay

1. Background

Frail older people are known to have a complex health status and therefore often complicated healthcare needs. In addition, a small group utilises a lot of healthcare from various agents (Condelius, Edberg, Jakobsson, & Hallberg, 2008). It may be difficult for the health system to meet the needs of frail older people (Clarfield, Bergman, & Kane, 2001) as it is a challenge for the health system to create coordinated healthcare and provide frail older people with preventive interventions (Young, 2003). In order to overcome problems with fragmented care and discontinuity, and to enable old people to have their complex needs met at an appropriate level, organisational interventions need to be developed and evaluated. Such interventions should aim to improve the older person's situation, with attention being given to cost-effectiveness and impact on healthcare utilisation (Medical Research Council, 2008). Frail older people are a heterogenic group and they may be in very different situations. Therefore, interventions should not just focus on a specific condition or a specific disease but identify each individual's specific needs (Hallberg & Kristensson, 2004). Case management is one such person-centred organisational model, but previous studies have reported contradictory results while healthcare utilisation has rarely been evaluated in terms of both inpatient and outpatient care. Thus a more comprehensive evaluation of the effects of case management on healthcare utilisation is needed.

Both health complaints (Persson et al., 2001) and healthcare utilisation increase with age (Nawar, Niska, & Xu, 2007), and several studies have shown that a small proportion of older people utilise a great proportion of the total of healthcare services. A Swedish study reported for instance that 15 per cent of the sample (aged 65+) (n=4907) had 3 or more hospital admissions, but counted for 35 per cent of the total admissions; in addition a high number of visits to physicians in primary care was a predictor of hospital admissions (Condelius et al., 2008). This means that older people utilise healthcare at several care levels. Furthermore, a United Kingdom (UK) study has reported that older people experienced the health system as being complicated and inaccessible because they did not know what they were entitled to or how to access information (Gott et al., 2007). Frail older people with complex needs may also be at risk of losing control over their healthcare situation because they need to manage contact with various kinds of healthcare agencies at different levels. A Swedish study reported that receiving healthcare and/or social services in Sweden in old age entailed a range of power positions (2010). Being in the hands of the organisation, a lack of continuity in healthcare or social services, being insecure, uninformed and without influence and feeling disappointed with unsatisfactory care and services contributed to feeling powerless. The authors also conclude that healthcare and services should be organised in accordance with the individual's life situation which requires information, accessibility and continuity (Kristensson, Hallberg, et al., 2010). This indicates that there is a need for person-centred interventions that increase the older persons' control over their healthcare situation.

To deal with increasing demand for healthcare and social services due to the increasing number of older people, many developed countries have, in recent decades, decentralised their health systems (Saltman & Bankauskaite, 2006). However, it has been argued that

decentralisation contributes to a severe risk of fragmentation (Åhgren, 2007) and it could be difficult for older people to orientate within a fragmented health system. For instance, it has been reported that older people are often admitted to emergency medical wards because of unfulfilled social and physical needs (Kirk & Hendriksen, 1982; Molloy, McGee, O'Neill, & Conroy, 2010). This implies that some admissions could be prevented if some of the older persons' needs could be met at a more appropriate level within the health system. However, this requires both preventive interventions and active coordination between healthcare agencies.

Different interventions have been developed with the aim of reducing the risk of fragmentation (Beland & Hollander, 2011). Preventive home visits is one such model, with these having been conducted since the early 1980s targeting for instance older people of a certain age (Hendriksen, Lund, & Stromgard, 1984), but with inconclusive results (Bouman, van Rossum, Nelemans, Kempen, & Knipschild, 2008; Elkan et al., 2001; Huss, Stuck, Rubenstein, Egger, & Clough-Gorr, 2008; Stuck, Egger, Hammer, Minder, & Beck, 2002; van Haastregt, Diederiks, van Rossum, de Witte, & Crebolder, 2000). One possible reason is that given frail older people's complex health situation, often with a presence of multiple diseases, preventive home visits targeting those of a certain age or single disease management programmes targeting those with a specific disease may not be sufficient. Thus, a broader and more holistic approach such as a case management programme may be necessary. According to The Case Management Society of America (Case Management Society of America, 2010), case management is "… *a collaborative process of assessment, planning, facilitation, care coordination, evaluation, and advocacy for options and services to meet an individual's and family's comprehensive health needs through communication and available resources to promote quality cost-effective outcomes.*" (p. 8). Therefore a case management programme

could aim at integrating the health system and reducing the risk of fragmentation as well as improving the older persons' overall situation in terms of solving problems and reducing different kinds of risk factors.

However, the reported effects of different case management programmes on healthcare utilisation are also contradictory. A randomised controlled study (n=654) showed that those receiving a case management intervention used fewer hospital bed-days (2003). In review of case management studies it was reported that there were two studies in which case management significantly decreased healthcare utilisation and costs (2009). On the other hand there were six studies without such effects (Oeseburg et al., 2009). There are also other studies that showed no effects on reductions in hospital admissions (Gravelle et al., 2007), emergency readmissions (Latour et al., 2007; Lupari, Coates, Adamson, & Crealey, 2011) or bed-days (Lupari et al., 2011). Because of the inconsistent results more research is needed to understand if, and under what circumstances, case management can be effective (Latour et al., 2007; Lupari et al., 2011; Oeseburg et al., 2009; Onder et al., 2007). Reasons for the inconclusive results could be the lack of an established definition and content of the concept of case management and that the interventions are rarely described in detail, making it difficult to compare different case management interventions (Markle-Reid et al., 2006; van Haastregt et al., 2000). Another source of differences in outcomes may be due to differences in samples and settings (Hallberg & Kristensson, 2004).

As a case management intervention may contain several components it could be considered to be complex. The complexity makes it difficult to develop, document, deliver and reproduce and it may also be hard to identify the "active ingredient" in the intervention (Medical Research Council, 2008). This, in turn, could also make it hard to pin-point in exactly which

areas the intervention is likely to be beneficial. It has been argued that one of the primary outcomes of a case management intervention for older people is a reduction of healthcare utilisation (Watt, 2001). However, as healthcare utilisation can be measured in many ways in both inpatient and outpatient care, any evaluation needs to consider several aspects and not just assess single variables.

The objective of this study was to investigate the of a case management intervention for frail old people (aged 65+ years) effects on healthcare utilisation.

2. Materials and Methods

The study was designed as an experimental two-armed randomised controlled trial (RCT) with repeated follow-ups (Shadish, Cook, & Campbell, 2002). It was carried out in the municipality of Eslöv in southern Sweden and was a collaborative study between municipal care and social services, primary care and a nearby university hospital.

2.1. Setting

The health system in Sweden is highly decentralised. In Sweden it is mainly the 20 county councils and 290 municipalities that provide healthcare and social services at regional and local levels respectively. Care and services in Sweden are based on a welfare system and are mainly funded by taxes (Molin & Johansson, 2005). Long-term care and social services are provided by the municipalities either at home or in special accommodation (i.e. nursing homes). The municipalities can also provide healthcare and are responsible for nursing home care (Lagergren, 2002). Physician home care, together with healthcare, treatment, rehabilitation and specialised medical care in inpatient, outpatient or in primary care centres,

is provided by the county council. According to the Social Services Act ("Hälso- och sjukvårdslag (*The Swedish Health and Medical Service Act*)," 1982), all people, including older people, who need help to support themselves in their day-to-day existence, have the right to claim for assistance and receive municipal care and/or social services “if their needs cannot be met in any other way” (The National Board of Health and Welfare, 2008) (p. 4). The decision is made by municipally-employed home-help officers based on a needs assessment (Lagergren, 2002). Long-term municipal care could comprise tasks such as help with cleaning, doing laundry, help with shopping, personal care, transport services, meals on wheels, bodily carried safety alarm and is provided in the older person’s home or in special accommodation (Lagergren, 2002).

The municipality in the study was medium-sized and had approximately 30 000 inhabitants in 2007. Within the municipality there was one town, with around 17 000 inhabitants, and 11 villages. The municipality contained both rural and urban areas as well as industrial and agricultural environments. The nearest hospital, which was also a university hospital, was approximately 20 km from the municipality town. The hospitals in the county were responsible for all in-patient care and, together with private specialist healthcare clinics, responsible for out-patient specialist care. Primary care centres, public or private, were responsible for all primary care. The municipality in the present study comprised three primary care centres and a private specialist healthcare clinic with medical services in, for instance, gynaecology, general orthopaedics, day surgery and physiotherapy.

2.2. Sample

A power calculation was made a priori with the mean change of hospital admissions as a primary outcome. A mean difference of 1.0 hospital admissions over 12 months was regarded

as clinically relevant and for 80 per cent power the power calculation showed that a total sample of 140 participants was needed. A continuous recruitment process was carried out from October 2006 to April 2010 to obtain the requisite numbers of participants. A total of 153 participants were randomly allocated to intervention (n=80) or control group (n=73) (Figure 1). The sample was consecutively recruited from three clinics at the university hospital (n=20), from three primary care centres in the municipality (n=117), through the municipal home care organisations (n=13) or by the participants contacting the research group by themselves (n=3). Inclusion criteria were that the participants should live in an ordinary home (i.e. not in for instance nursing homes or sheltered housing) in the municipality chosen for the study, be aged 65 years or older, be dependent in at least two activities of daily living and have been admitted to hospital at least twice or had at least four visits in outpatient or primary care during the previous 12 months. The visits could have been conducted in public- and/or private healthcare, in primary- and/or in out-patient specialist care. People who were not able to communicate verbally, had cognitive impairments or had moved to special accommodation were excluded. Cognitive impairment was examined by using the Mini Mental State Examination (MMSE) (Folstein, Folstein, & McHugh, 1975) with a cut-off of 25 points or higher out of a maximum of 30 as a requirement for participating in the study. At the university hospital the nurses in the case management programme screened the three clinics, as well as recruited and informed the potential participants about the study while in primary care, and in municipal care the staff asked the potential participants whether they would allow someone from the research team to contact them to see if they met the inclusion criteria and to provide more information about the study. A different recruitment procedure was also used in primary care where potential participants fulfilling some of the inclusion criteria were contacted. All those 65 years or older with four or more visits in primary care were contacted by the research team by telephone or by mail with information about the study. Those

contacted by mail also got a reply form and a prepaid envelope and were asked whether or not they agreed to allow the research team to contact them by telephone in order to give additional information and to investigate whether or not they also met the ADL inclusion criteria. A total of 1,079 people were approached (862 through mail or telephone in the primary care recruitment procedures). Of those approached 926 were excluded, of which 7 died before randomisation, 231 did not meet the inclusion criteria and 688 could not be randomised. The reason for not being randomised was either that they had not responded to the screening letter and thus not possible to determine if they fulfilled the inclusion criteria (n=571), they did not want to participate (n=71), it was not possible to contact them (n=28), or they were too tired or too ill (n=18) (Figure 1). The randomisation included sealed envelopes containing information about the group to which they had been assigned, with equal chances of being allocated to each group. The simple randomisation procedure was performed by the research team. A total of 153 underwent baseline measurement. At baseline, information about the project was repeated once more, after which the participant provided informed written consent. The study ended in April 2011 and during the 12-month study period 45 persons died or declined further participation leaving 108 completing the study (Figure 1).

< Insert Figure 1 about here >

The study was conducted in accordance with the Helsinki declaration (World Medical Association Inc, 2009) and the study was approved by the regional Ethics Review Board in Lund (Nos. 342/2006 and 499/2008). All participants provided written informed consent both for participating in the intervention study and for the use of healthcare utilisation registers.

2.3. The intervention

This study has been developed according to the first version of the Medical Research Council's framework for development and evaluation of RCTs for complex interventions to improve health (Medical Research Council, 2000). The pilot study of the RCT, in which the development and the content of the intervention is also described in detail, has been published (Kristensson, Ekwall, Jakobsson, Midlov, & Hallberg, 2010). The intervention differed from the pilot study in that there were also additional home visits from physiotherapists. The main reasons were that falls and a low degree of physical activity were seen as big problems among older people living at home. Depending on the number of participants, one or two nurses and one or two physiotherapists were employed on a part-time basis as case managers. The employed members of staff had experience of caring for, or rehabilitating older people in geriatric wards or in community settings.

The case management programme in the present study essentially comprised four different parts: *"traditional" case management* (assessment, care coordination, home visits, telephone calls, advocacy), *general information* (about the healthcare system, social activities, nutrition, exercise etc.), *specific information* (related to the participant's specific health status, individual needs and medication) and *safety* (the availability of the nurse or physiotherapist by cell phone during working hours) (Kristensson, Ekwall, et al., 2010).). The part of the programme carried out by the case managers with nursing background focused more on nursing care, on the participant's health and on making and evaluating a care plan while case managers with physiotherapy background focused more on the prevention of falls (balance training, home adaption, aids etc.), and on increasing physical function. The nurses also made an evaluation of the participant's prescribed medication. One of the physicians in the project also reviewed medications for both the intervention and the control group. The case manager

visits took place in the participants' own homes and were performed at least once a month during the 12-month intervention programme and started after the participants had been assessed at baseline by the researchers. If needed the case managers sometimes also performed visits at hospitals or short time accommodations. The content of the home visit depended on the participant's needs and the CMs care plan. Each visit lasted generally about an hour, but sometimes longer.

At the first home visit the CMs with nursing background made an initial assessment using the Minimum Data Set for Home Care (MDS-HC) (Landi et al., 2000; Morris et al., 1997), which is a comprehensive geriatric assessment tool. The first assessment was followed by re-assessments on each visit in order to be able to identify possible intervention areas. For each participant a care plan was developed, monitored and followed up at the later visits (Kristensson, Ekwall, et al., 2010). The CM with physiotherapy background evaluated the participant's functional status through anamnesis (questions about diseases, activities/activity levels and aids), and assessments using the General Motor Function assessment scale (GMF) (Åberg, Lindmark, & Lithell, 2003). To evaluate the participant's physical function the physiotherapist CM also used the Berg Balance Scale (BBS) (Berg, Wood-Dauphinée, Williams, & Gayton, 1989) and Fukuda Stepping Test (Fukuda, 1959) respectively. Assessments of the vibration sensations in the lower limbs were also performed (Kristinsdottir, Jarnlo, & Magnusson, 1997). The purpose of using these measurements was not to measure any intervention effects. This information was used by the physiotherapist, together with information from the nurse about other disabilities of the participants, to develop an individual physical training programme depending on the participant's physical ability and risk of falling. The participants performed the programme on their own and the physiotherapist made follow-ups at least once a month to support and adjust the programme.

In addition, if any problems were detected, the nurses and the physiotherapists were able to contact one of the physicians in the project. This contact was also available for the control group if the researchers discovered any problems. Solutions in particularly difficult cases were regularly discussed in meetings between the nurses, physiotherapists and the research group (Kristensson, Ekwall, et al., 2010).

In general the CMs conducted one visit every month. It usually took some weeks before the CMs conducted their first visit. Some visits during the intervention program were also cancelled due to the participant being too sick. During the 12 month intervention the nurse made an average of 11.1 home visits and 1.9 telephone calls, and the physiotherapist 10.4 visits and 0.8 telephone calls for those completing the intervention period. For attritions (Figure 1) the mean intervention time was 5 months and they received an average of 3.7 visits and 1.0 telephone calls from the nurse and 2.5 visits and 1.0 telephone calls from the physiotherapist respectively.

2.4. Data collection

Structured interviews were carried out in both groups at baseline and every third month in the space of one year by researchers working independently of the nurses and physiotherapists. The interviews covered background data, social aspects, health status, health related quality of life and life satisfaction and care and services (such as home care and health services from the county, municipal and next of kin and/or other informal caregivers) (Kristensson, Ekwall, et al., 2010). After the pilot study, questions about balance and physical activity were added. In the present study baseline data from the structured interviews were used for comparisons between groups. The baseline data comprised demographics (age, gender, municipal care,

marital status, having children), socioeconomics (educational level and financial status), the number of self-reported diagnosis groups during the last three months according to diagnosis groups in WHO's ICD-10 (World Health Organisation, 2007), self-reported health complaints in the last three months (Stenzelius, Westergren, Thorneman, & Hallberg, 2005), functional status assessed with the ADL staircase (Åsberg & Sonn, 1989), risk of depression assessed with the 20 item version of the Geriatric Depression Scale (GDS-20) (Gottfries, Noltorp, & Norgaard, 1997) and cognitive status assessed with the Mini Mental State Examination (MMSE) (Folstein et al., 1975).

Data concerning healthcare utilisation provided in the county were collected from two patient administrative registers: Patient Administrative Support in Skåne (PASiS) for all publicly organised inpatient and outpatient healthcare in the county of Region Skåne and PrivaStat for all privately organised care. In these systems, individual data concerning healthcare utilisation are registered. Variables used in this study were for inpatient care: the number of acute and planned hospital admissions, length of stay (LOS), inpatient diagnosis, and for outpatient care: number of contacts with physician and other healthcare members of staff (nurses, physiotherapists, occupational therapists, etc.), medical specialty and whether or not the visit was at an emergency department. An acute admission is when an admission, among all actual admissions, was acute, in contrast to a planned admission. An acute admission could occur at any ward at the hospital and was registered as inpatient care. Visits at the emergency department are registered as outpatient care, and may or may not later lead to an admission. The variables were collected for dates one year before, and one year after the baseline interview. Inpatient data were registered either as somatic admission or psychiatric admission. Outpatient data in PASiS comprises contacts with physicians in somatic care (i.e. outpatient specialist care outside primary care), primary care, medical services (i.e. contacts with X-ray,

laboratories etc.), special dental care and psychiatric care. For other healthcare staff providing outpatient care, the data comprises somatic care (i.e. outpatient specialist care outside primary care), primary care, medical services, habilitation and psychiatric care. Privately organised care included both primary care and out-patient specialist care. In this study contacts with physicians in outpatient care included private and public somatic/specialist care and primary care. An outpatient contact could either consist of a face to face visit, a telephone call or another form of contact (e.g. letter or e-mail). Each admission or visit causes a new registration. An individual could have several registrations for one period due to a change of clinic during the hospital stay. In the present study a hospital stay was considered as a continuous stay and has one date for admission and one date for discharge regardless of the number of registrations. The diagnosis that was registered followed the International Classification of Diseases 10th Revision (ICD-10) (World Health Organisation, 2007). Fifteen diagnoses could be registered in PASiS for one contact. The primary code is assumed to be the main reason for the registration. As each hospital visit could also yield several registrations, an individual could have several primary diagnoses for each hospital stay. The data were entered by administrative and/or healthcare staff.

The baseline data from the intervention study was merged with the healthcare utilisation data from PASiS and PrivaStat.

2.5. Statistical analysis

The control and intervention groups were compared regarding demographics, socioeconomics, self-reported diagnosis groups, self-reported health complaints, activities of daily living (ADL), risk of depression and cognitive impairment. Healthcare utilisation was compared between the intervention and control group regarding inpatient care (number of

visits and LOS) and outpatient care (contacts with physicians and other professionals). For inpatient care the hospital stays were not divided into somatic and psychiatric admissions. The reason for this was that all hospital stays but one, a four day admission, were in somatic care. For outpatient care the type of contacts are presented as visits, telephone calls and as a total. Other kinds of contact are included in the total number of contacts. Healthcare utilisation data were analysed for one year before inclusion in the study as well as during the whole intervention year. The health utilisation data were divided into four time periods, 6-12 months, and 0-6 months before baseline as well as 0-6 months, and 6-12 months after baseline and compared separately. Numbers of diagnoses for inpatient data were calculated as the total of primary diagnosis in all hospital stays. This was calculated for both primary diagnosis and for all registered diagnoses for the year before baseline as well as the year after baseline. Comparisons were made using Chi-squared for nominal data, the Mann-Whitney U-test for ordinal data and Student's t-test for interval and ratio data.

The analyses were made according to the Intention-To-Treat principle (ITT) (Altman, 1991). Attritions during the first 6 months after baseline (n=26) were for this period given their registered values and for the subsequent period, 6-12 months after baseline, given their last known value in accordance with the last-observation-carried-forward (LOCF) (Wood, White, & Thompson, 2004). A complete case analysis was also conducted (Bennett, 2001).

Effect sizes (ES) were calculated for all significant results and was calculated as ES = $(m_1-m_2)/s_1$, where m_1 is a pre-treatment mean, m_2 the post-treatment mean and s_1 the pre-treatment standard deviation (Kazis, Anderson, & Meenan, 1989). In this study two ES was calculated for each significant difference, using the significant value as m_2 and the two pre-treatment values as m_1 respectively. ES was also calculated for both the intervention- as well as the

control group. Effect size interpretation was based on the nomenclature suggested by Cohen (1977) where 0.2 represents a small, 0.5 a medium and 0.8 a large effect. In the present study a positive effect size means a reduction in healthcare utilisation.

3. Results

No significant differences between intervention and control group were found in demographics or socioeconomics at baseline (Table 1). There were no significant differences between intervention and control groups in the number of self-reported diagnosis groups, in the number of self-reported health complaints, in the five most common self-reported health complaints, in functional dependency, in the risk of depression or in cognitive impairment at baseline (Table 2).

< Insert Table 1 about here >

< Insert Table 2 about here >

A total of 263 primary diagnoses were registered and the most common primary diagnosis (in ICD-10 codes) groups 12-0 months before baseline in the intervention group were: atrial fibrillation and flutter (I48) (n=7), acute myocardial infarction (I21) (n=5) and pain in throat and chest (R07) (n=5) and, in the control group, heart failure (I50) (n=5), I21 (n=4) and other chronic obstructive pulmonary disease (J44) (n=4). The most common primary diagnosis groups 0-12 months after baseline were in the intervention group atrial fibrillation and flutter (I48) (n=9) and heart failure (I50) (n=6) and, in the control group, cerebral infarction (I63) (n=4), pneumonia, organism unspecified (J18) (n=3) and other chronic obstructive pulmonary

disease (J44) (n=3). For all registered diagnosis groups, for both primary and secondary diagnosis (n=862), the most common registered diagnosis groups 12-0 months before baseline were, in the intervention group essential (primary) hypertension (I10) (n=25) and atrial fibrillation and flutter (I48) (n=17) and, in the control group, essential (primary) hypertension (I10) (n=25) and atrial fibrillation and flutter (I48) (n=18). In the period 0-12 months after baseline the most common diagnosis groups were in the intervention group atrial fibrillation and flutter (I48) (n=23) and heart failure (I50) (n=11) and in the control group atrial fibrillation and flutter (I48) (n=17) and essential (primary) hypertension (I10) (n=16).

No significant differences were found between groups regarding inpatient care in terms of hospital stays or LOS (Table 3) and no significant differences were found regarding the mean number of total emergency department visits or the mean number of EDs leading to hospitalisation (Table 3). There was a significantly lower mean number of emergency department visits (ED) not leading to hospitalisation in the intervention group 6-12 months after baseline, compared with the control group (0.08 vs. 0.37, p=0.041) (Table 3). This was also seen when investigating the proportion of EDs visits not leading to hospitalisation with a significantly lower proportion in the intervention group, 6-12 months after baseline (17% vs. 47%, p=0.016) (Table 3), meaning that those in the control group was sent home in a higher extent than the intervention group. The corresponding ES were for the interventions group 0.28 and 0.19 (6-12 months before baseline compared to 6-12 months after baseline, and 0-6 months before baseline compared to 6-12 months after baseline respectively), while a negative effect, -0.42 and -0.23 respectively, was found in the control group.

There was a significant difference for mean numbers visits to physician in outpatient care between the intervention and control group 6-12 months after baseline (4.09 vs. 5.29,

p=0.047) (Table 3). For the intervention group the ES between 6-12 months before baseline and 6-12 months after baseline were 0.33 and, for the control group, 0.05. The ES between 0-6 months before baseline and 6-12 months after baseline were 0.31 and 0.19 in intervention- and control group respectively. There were no significant mean differences in contacts with other professionals in outpatient care.

< Insert Table 3 about here >

When conducting a complete case analysis the results regarding differences between intervention and control group some results changed. When comparing the groups without attritions (intervention group n=65, control group n=62) with the ITT-analysis there were a significant difference between intervention- and control group for telephone contacts with physician in outpatient care 6-12 months after baseline, with a higher number for the control group compared with the intervention group (3.03 vs. 1.08, p=0.037). Compared to the ITT-analysis there were no significant differences for mean numbers of visits to physician in outpatient care for 6-12 months before baseline (intervention group 4.02, control group 5.25, p=0.055) or ED visits not leading to hospitalisation (intervention group 0.06, control group 0.37, p=0.056). The number of attritions did not differ in the two groups (p=0.546) and the attritions in both groups did not differ significantly regarding age (p=0.460), sex (p=0.128), municipal care (p=0.711), marital status (p=0.503), having children (p=0.313), or economic status (p=0.316) at baseline. There were no significant differences in the number of self-reported diagnosis groups (p=0.941), in the number of self-reported health complaints (p=0.491), functional dependency (p=0.276), risk of depression (0.461) or cognitive impairment (p=0.198) at baseline. The attritions had a significant higher educational level at baseline (p=0.028).

4. Discussion

No significant differences were found for total hospital admissions or LOS. One reason for this could be that the participants had a medical condition which required hospitalisation and that could not be prevented. The main reasons for hospitalisation were circulatory diseases and respiratory diseases. In this group of frail older people these conditions may not be preventable and this intervention may therefore not be sufficient to avoid hospitalisation. It may also be that the case managers found an unmet need for healthcare resulting in an increase of healthcare utilisation. It has been reported that preventive programmes could satisfy an unmet healthcare need and as such be the reason for increased healthcare utilisation (2005). Therefore, intervention programmes could tend to be less cost-effective while, in fact at the same time resulting in increased well-being among older persons. It has been reported that outreach case management programmes may find people with a demand for healthcare and social services that were unknown to the healthcare organisations (Evercare, 2004). Therefore, the intervention may have worked from an individual point of view and have been successful because previously unnoticed conditions were identified. There is also a possibility that there is a shift of resources, with reduction in healthcare in some areas and an increase in other. Thus, when evaluating an intervention, such as the one in this present study, the focus should not solely be on healthcare utilisation, but also include variables that, for instance, healthcare costs and quality of life. This was, however beyond the scope of this study. Only few other studies have reported effects on hospital admissions or LOS. One Italian study (Bernabei et al., 1998) found a small significant decrease in hospital admissions as well as LOS, and an Australian prospective multicentre, randomised controlled trial (Lim et al., 2003) found a significant difference in LOS between the intervention group and the control group

(3.0 vs. 5.2, $p<0.01$). But as in the present study several other studies found no such effects (Gagnon, Schein, McVey, & Bergman, 1999; Gravelle et al., 2007; Lim et al., 2003; Long, 2002; Newcomer, Maravilla, Faculjak, & Graves, 2004). Thus, the intervention did not have an effect on inpatient care in terms of admissions or LOS, but from an older person's perspective an unmet need may have been met. This is why further research about underlying aspects of the results is needed in the future.

The results showed that there was a significantly higher number of participants in the control group that were not hospitalised after an ED visit, meaning that they were sent home in a greater extent. This was seen both in the proportion of ED visits, in the mean number (Table 3) and was also shown in the effect size. It is possible that those in the control group visited the ED with a condition that did not required hospitalisation. It might also be an indication of their health status having been poorly monitored so that the intervention filled an important function by solving problems that, if unsolved, may have caused an increase in ED visits. Also when the intervention group did actually seek acute care, their health problems may have required hospitalisation. It is also reasonable to believe that the home visits and support of the case manager played an important role in terms of noticing potential problems and showing ways to deal with different problems. Furthermore, the participants in the intervention group also had the possibility of consulting the case manager when they experienced any problems. There are studies that have shown that case management interventions for the frail elderly reduced the number of ED visits. The Italian RCT (1998) reported a small but clinically relevant reduction in ED visits with a hazard ratio of 0.64 (95% CI 0.48-0.85, $p<0.025$). In an English study the median acute admission decreased from 1.48 during the 12 months prior to their initial case manager visit to 0.5 in the 12 months after the first visit ($p=0.03$) (Moran, Coleman, Heaney, & Willcocks, 2008). Other studies, however, found no effects on ED visits

(Gagnon et al., 1999; Gravelle et al., 2007; Long, 2002; Newcomer et al., 2004). The present study was a more comprehensive home-based case manager intervention, with home visits at least once every month. In the Italian study (Bernabei et al., 1998), that showed effects in healthcare utilisation, the case manager made a visit every second month and they were available for problem solving between the visits. In other studies reporting no effects on ED visits, the case manager was reported to have had fewer contacts than in the present study and the Italian study (Bernabei et al., 1998). For instance, one study (Newcomer et al., 2004) reported an average of 7.7 contact hours during the one year intervention and another study (2002) reported that the case managers had made at least one home visit every 6 months. In the study by (Gravelle et al., 2007) no preventive home visits seem to have been made at all. Another factor that may have contributed to the effect of the intervention in this present study could be the interdisciplinary team, with a nurse and a physiotherapist. This was also reported in two studies with effects on healthcare utilisation (Bernabei et al., 1998; Moran et al., 2008) where the case managers worked in interdisciplinary teams. The result indicates that home visits made on a monthly basis and interdisciplinary case management in the present study may have had an effect on frail older people with regard to ED visits.

The intervention group reported a lower mean number of to physicians in outpatient care for 6-12 months after baseline compared with the control group (Table 3). The results together with a small to moderate ES indicate that the intervention may have been effective also with regard to visits to physician in outpatient care. The reason for this may be that the nurse and the physiotherapist served as a form of support and were able to coordinate the care and solve problems in the participants' own homes instead of in an outpatient care setting. A Dutch RCT (Latour et al., 2007) investigated the effects of a nurse-led case management intervention and found significant differences in visits to the practice of a general practitioner

(mean 3.0, SD. 3.9 vs. 1.6 SD. 3.0, p=0.05) but not for the total number of contacts, telephone contacts, home visits or visits to other professionals. In the Italian study (Bernabei et al., 1998) significantly more home visits by general practitioners were needed in the control group (13.1 SD. 0.8 vs. 10.2 SD. 1.1, p=0.04). There were also studies that were unable to show significant differences in visits to physician in primary care and on the total of outpatient visits respectively (Long, 2002; Newcomer et al., 2004). This may be due to whether or not the interventions were hospital-based or community-based. Several hospital-based interventions (Gagnon et al., 1999; Latour et al., 2007; Lim et al., 2003; Newcomer et al., 2004) showed no or little effect on healthcare utilisation while community-based interventions (Bernabei et al., 1998; Long, 2002; Moran et al., 2008) seemed to be more efficient in terms of decreased outpatient utilisation. The results may indicate that the case manager in community-based interventions has the possibility of working closely with frail older people in their own homes to solve some of the problems and to be able to evaluate via the continuous follow-ups, thus being able to help the person get in touch with primary care or emergency care if needed. It is therefore reasonable to believe that home-based case manager programmes should be based in the community and that case managers should work in close collaboration with primary care. However, it is important that the case managers also have knowledge about the health system in its entirety so that they will know where, how and when they could contact different healthcare agencies. On the other hand, if the lowered number of contacts with a physician was caused by the case manager's ability to solve some of the older person's problems, this would be highly valuable both for the frail older person as well as for the health system.

The studied population was heterogeneous in aspects of healthcare utilisation. Some participants fulfilled the healthcare utilisation inclusion criteria by having at least four visits to

physician in outpatient care and some by have being admitted to hospital at least twice. A large proportion of the sample where recruited from primary care centres. This means that they were known to be high users of primary care and this area was therefore more likely to be affected and that this could be one reason for the significant reduction in visits to physicians in outpatient care. We may have had a different outcome if the entire sample were recruited from inpatient care. More research is therefore needed in populations of older people with different healthcare utilisation patterns. Furthermore, there is a risk that there was a shift of resources from in- and outpatient healthcare to informal care or healthcare provided by the municipalities, like for instance how many that moved to special accommodations or utilisation of home healthcare. These aspects were however beyond the scope of this study, but were nonetheless a limitation.

Internal validity and the randomising process are important aspects when conducting an RCT. There were no significant differences between the intervention and the control group at baseline (Table 1 and 2). The similarities eliminate threats to internal validity such as history, maturation and testing (Polit & Beck, 2012). Many people received information about the study through the screening/recruitment processes, but only 48 per cent of those approached agreed to be contacted. Of those contacted and eligible for inclusion, 45 per cent declined participation before randomisation due to illness, death, being out of reach or unwilling to participate (Figure 1). It is unknown how many of those contacted only by mail, on the basis of the number of their visits in primary care, were eligible and what their reasons for not participating were. In the pilot study preceding the present study (Kristensson, Ekwall, et al., 2010) the sampling procedure was considered to be feasible. In some cases the participants changed their minds after initially having agreed to participate, for example when the participant became severely ill before the baseline interview. The sample had several diseases

and health complaints, and attrition caused by declining health or death (Figure 1) is a threat to both internal and external validity. The attrition rate was 16 per cent after 6 months and 26 per cent after 12 months. In spite of this and the aspect that the frailest older people may have declined participation, the group of older people in the present study were very frail, with a high mean age, several self-reported diagnoses (median 3 vs. 4 in the intervention and control group respectively), many self-reported health complaints (median 11 in both groups) and a high score on the GDS-20. Thus, the present study succeeded in capturing the group of frail older people targeted. This, together with the study design and the equality between the intervention group and the control group, makes it reasonable to believe that there were no major threats in terms of internal and external validity in this study.

As the attritions were a threat to internal validity, analyses were conducted with Intention-To-Treat (ITT) (Polit & Gillespie, 2010). The imputations technique LOCF was chosen because of the ease with which it can be accomplished. One underlying assumption is that the attritions should be missing completely at random (MCAR) otherwise the result could be seriously biased (Bennett, 2001). No significant differences between the attritions in the two groups were found, indicating that the assumption of MCAR has not been violated. Small differences in mean values between the ITT-analysis and the complete case analysis were found which also suggests that the attritions were MCAR. Since there were only small differences in the mean values between the ITT and the complete cases analysis the differences in significances between the analyses may depend on lower power in the complete cases analysis. The chosen imputation technique therefore seems reasonable and the bias due to this method could be considered to be low.

Another problem, related to construct validity and replication, is the question about how the intervention works and which component(s) that is effective. This has also been addressed as one of the difficulties when studying complex interventions (Medical Research Council, 2008). One way to deal with this issue is to follow the framework suggested by the British Medical Research Council (MRC), to explore the intervention from various perspectives, with quantitative, qualitative as well as economic evaluations, and to give as rich description of the intervention as possible (Medical Research Council, 2008). This case management intervention followed the MRC framework and comprehensive description of the intervention has been included in this study. In addition, a qualitative study, consisting a content analysis of receivers' of case management (older people's) and the case managers' experiences, has been published (Sandberg, Jakobsson, Midlov, & Kristensson, 2014). The analysis gave two content areas: providing/receiving case management as a model and working as, or interacting with, a case manager as a professional. The results constituted four categories: case management as entering a new professional role and the case manager as a coaching guard, as seen from the provider's perspective; and case management as a possible additional resource and the case manager as a helping hand, as seen from the receiver's perspective. The findings could be related to the different components of case management, but also how the intervention was delivered, i.e. through home visits or that there were barriers that made it difficult to deliver the interventions as intended. The study showed that the case manager could be experienced as a "helping hand" in terms of monitoring and coordinating care, that are related to case management determinants, and in terms of various more practical conditions, such as making home visits, as this gave the ability to discover problems and monitoring the older person's situation (Sandberg et al., 2014). The interpretation is that interventions elements interact and that it is not possible to distinguish the effects of specific intervention determinants. It is not always the key question but rather whether the intervention

as a whole works in everyday practice (Medical Research Council, 2008). Furthermore, the MRC framework also recommends process evaluation, as this could give insight into key determinants and why an intervention fails, how it works and can be optimized, and how to assess fidelity and quality of implementation of the intervention (Medical Research Council, 2008). A process evaluation could contribute to a wider understanding and interpretation of the intervention, its key determinants and the results in this study, and may also facilitate replication. However, this was beyond the scope of this study and needs to be addressed in future research.

The data used for healthcare utilisation came from PASiS and PrivaStat. The validity of the Swedish national inpatient register (IPR), of which PASiS and PrivaStat are parts, has recently been investigated in a review of 132 papers (Ludvigsson et al., 2011). They compared ICD codes from the IPR with information in the medical records and found that the predictive values were 85-95 per cent for most diagnoses and for patients dying in hospital the agreement between their IPR primary discharge diagnosis and the underlying cause of death was good (around 90%). The registers covered the county of Skåne and there is a possibility that the participants have utilised healthcare in another county council. There is also a risk that not every visit was registered, but since the registrations form the basis for reimbursement to the different health agencies this risk is considered to be small. However, by combining the different registers with the data from the RCT, unique information was obtained about the effects of a home-based case manager intervention.

5. Conclusion

It seems that the case management intervention in the present study had some effect on healthcare utilisation by reducing visits to physicians in outpatient care and to emergency departments. The benefits of the intervention should, however, be interpreted carefully. A reduction in healthcare utilisation is important from an organisational point of view, but it is not necessarily something positive from the individual's perspective. Reduced care is only positive if the individual's healthcare needs have been reduced. The case managers could also have discovered unmet health needs that required healthcare resulting in increased healthcare utilisation. Therefore, more research is needed to investigate how case management interventions affect frail older people on an individual level, for instance on quality of life or perceived health. More studies are also needed to investigate effects on healthcare costs, because it is possible that the reduction is due to a shift of utilisation of resources. However, from an organisational point of view, a reduction in healthcare utilisation could be seen as worth striving for and our findings are therefore important and clinically relevant.

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7. Conflict of interest statement

No conflicts of interest.

8. Authors' contributions

MS participated in the design of the study, in the collection of data, performed the statistical analysis and interpretation of data and drafted the manuscript. JK participated in the design of the study, participated in the data collection, helped in the interpretation of data and drafting of the manuscript. PM participated in the design of the study and helped to draft the manuscript. UJ participated in the design of the study, helped in the analysis and interpretation of data and the drafting of the manuscript. All authors read and approved the final manuscript.

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Table 1: Demographics and socioeconomic status at baseline

Group	Intervention (n=80)	Control (n=73)	p-value
Demographics			
Age, mean (SD)	81.4 (5.9)	81.6 (6.8)	0.795[a]
Women, n (%)	52 (65.0)	50 (68.5)	0.648[b]
Municipal care at baseline, n (%)	30 (37.5)	24 (32.9)	0.550[b]
Marital status, n (%)			0.338[b]
- Married or living together	23 (28.8)	29 (39.7)	
- Widow/er	41 (51.3)	34 (46.6)	
- Divorced or living apart	8 (10.0)	7 (9.6)	
- Other	8 (10.0)	3 (4.1)	
Having children, n (%)	67[§] (84.8)	67 (91.8)	0.184[b]
Socioeconomics			
Educational level, n (%)			0.437[c]
- Primary <8 years	40 (50.0)	31 (42.5)	
- Secondary >8 years	32 (40.0)	35 (47.9)	
- Third level/university	8 (10.0)	7 (9.6)	
Financial status, n (%)[†]			0.477[c]
- Better than others	16 (21.1)	10 (14.7)	
- Same as others	51 (67.1)	50 (73.5)	
- Worse than others	9 (11.8)	8 (11.8)	

[§)] Missing=1 [†)] Missing: Intervention group=4, Control group=5 [a)] Student's t-test [b)] Chi-square test [c)] Mann-Whitney U-test

Table 2: Self-reported diagnosis groups, self-reported health complaints, ADL, risk of depression and cognitive impairment at baseline

Group	Intervention (n=80)		Control (n=73)		p-value
Self-reported diagnosis groups					
Number of diagnosis groups, median (q1-q3)	3	(2-4)	4	(3-5)	0.163[a]
Range	1-8		1-7		
Self-reported health complaints					
Number of complaints, median (q1-q3)	11	(7-15)	11	(8-15)	0.655[a]
Range	2-22		2-23		
Five most common complaints, n (%)					
- Walking problems	55	(68.8)	55	(75.3)	0.365[b]
- Pain in the musculoskeletal system	55	(68.8)	52	(71.2)	0.738[b]
- Breathlessness	47	(58.8)	40	(54.8)	0.622[b]
- Fatigue	45	(56.3)	41	(56.2)	0.991[b]
- Memory impairment	41	(51.3)	42	(57.5)	0.436[b]
Activities of daily living					
Dependency in no. of ADL activities, median (q1-q3)	2	(1-3)	2	(1-3)	0.651[a]
- IADL	0	(0-0.8)	0	(0-0.5)	0.881[a]
- PADL	2	(1-3)	2	(1-3)	0.831[a]
- Total ADL					
Risk of depression					
GDS-20, median (q1-q3)	6.0[§]	(3.0-8.0)	6.0	(4.0-8.0)	0.824[a]
Cognitive impairment					
MMSE, median (q1-q3)	28.0	(27.0-29.0)	28.0[†]	(27.0-29.0)	0.571[a]

[§)] Missing=2 [†)] Missing=1 [a)] Mann-Whitney U-test [b)] Chi-square test

Table 3: Inpatient care, emergency department visits, and contacts with physicians in outpatient care for the intervention and control groups

	6 to 12 months before baseline			0 to 6 months before baseline			0 to 6 months after baseline			6 to 12 months after baseline		
	Intervention	Control	p-value	Intervention	Control	p-value	Intervention	Control	p-value	Intervention	Control	p-value
Inpatient care												
No. of hospital stays, mean (SD)												
- Total	0.38 (0.64)	0.45 (0.91)	0.545[a]	0.48 (0.84)	0.62 (1.14)	0.381[a]	0.40 (0.69)	0.40 (0.91)	0.983[a]	0.49 (0.81)	0.48 (0.84)	0.952[a]
- Acute	0.29 (0.60)	0.37 (0.83)	0.478[a]	0.40 (0.79)	0.45 (0.85)	0.695[a]	0.30 (0.62)	0.30 (0.70)	0.990[a]	0.39 (0.72)	0.42 (0.71)	0.748[a]
- Planned	0.09 (0.28)	0.08 (0.28)	0.907[a]	0.08 (0.31)	0.16 (0.65)	0.285[a]	0.10 (0.34)	0.10 (0.45)	0.949[a]	0.10 (0.34)	0.05 (0.28)	0.377[a]
Length of stay, mean (SD)												
- Total	2.14 (6.15)	2.79 (6.83)	0.532[a]	5.05 (12.74)	3.90 (7.26)	0.501[a]	2.38 (5.34)	1.78 (4.63)	0.466[a]	4.60 (15.42)	4.05 (11.71)	0.807[a]
- Acute	1.31 (3.95)	2.21 (5.61)	0.261[a]	4.49 (12.56)	3.29 (6.92)	0.471[a]	1.71 (4.26)	1.63 (4. 59)	0.909[a]	3.80 (15.01)	3.90 (11.54)	0.962[a]
- Planned	0.83 (4.34)	0.59 (2.47)	0.684[a]	0.56 (2.53)	0.62 (2.28)	0.890[a]	0.66 (3.46)	0.15 (0.78)	0.202[a]	0.80 (3.65)	0.15 (0.81)	0.125[a]
Outpatient care												
Emergency department visits												
No. of visits, mean (SD)												
- Leading to hospitalisation	0.25 (0.56)	0.32 (0.72)	0.534[a]	0.39 (0.79)	0.36 (0.71)	0.798[a]	0.24 (0.58)	0.25 (0.64)	0.927[a]	0.34 (0.69)	0.42 (0.71)	0.672[a]
- Not leading to hospitalisation	0.23 (0.53)	0.18 (0.45)	0.557[a]	0.15 (0.36)	0.22 (0.65)	0.412[a]	0.15 (0.51)	0.15 (0.54)	0.994[a]	**0.08 (0.27)**	**0.37 (1.18)**	**0.041[a]**
- Total	0.48 (0.76)	0.49 (0.88)	0.892[a]	0.54 (0.93)	0.58 (1.13)	0.820[a]	0.39 (0.80)	0.40 (0.91)	0.944[a]	0.41 (0.77)	0.79 (1.59)	0.066[a]
Number of visits, n (%)												
- Total	38	36		43	42		31	29		23	49	
- Not leading to hospitalisation	18 (47.4)	13 (36.1)	0.327[b]	12 (27.9)	16 (38.1)	0.318[b]	12 (38.7)	11 (37.9)	0.951[b]	**4 (17.4)**	**23 (46.7)**	**0.016[b]**
Contacts with physicians in outpatient care												
No. of contacts, mean (SD)												
Visits	5.49 (4.22)	5.45 (3.51)	0.955[a]	5.30 (3.94)	6.10 (4.20)	0.229[a]	4.55 (2.98)	4.78 (3.63)	0.667[a]	**4.09 (2.63)**	**5.29 (4.45)**	**0.047[a]**
Telephone calls	3.14 (3.47)	3.12 (4.07)	0.981[a]	2.96 (4.09)	3.34 (3.93)	0.560[a]	2.55 (3.20)	2.82 (3.88)	0.545[a]	2.10 (2.60)	2.84 (3.88)	0.167[a]
Total	10.79 (6.67)	10.12 (7.54)	0.564[a]	10.73 (7.49)	11.49 (6.83)	0.518[a]	9.68 (6.03)	9.36 (6.84)	0.760[a]	8.81 (5.99)	10.18 (8.18)	0.245[a]

[a)] Student's t-test [b)] Chi-square test

Significant differences are highlighted in bold.

Figure 1: CONSORT Flow Diagram